SENATE BILL No. 270

DIGEST OF INTRODUCED BILL

Citations Affected: IC 5-10-8-14.7; IC 12-7-2; IC 12-15-35.5-9; IC 27-8-32.2; IC 27-13-7-20.3.

Synopsis: Coverage for abuse deterrent opioids. Requires that, if an abuse deterrent opioid analgesic is available with a certain active ingredient, state employee health plans, Medicaid, policies of accident and sickness insurance, and health maintenance organization contracts must provide coverage for at least one abuse deterrent opioid analgesic that provides that active ingredient.

Effective: July 1, 2016.

Merritt

January 7, 2016, read first time and referred to Committee on Health & Provider Services.

Introduced

Second Regular Session 119th General Assembly (2016)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2015 Regular Session of the General Assembly.

SENATE BILL No. 270

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 5-10-8-14.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 14.7. (a) This section applies to a state employee health plan that provides coverage for prescription drugs, whether directly or through a formulary, a drug list, or another similar method.**

(b) As used in this section, "abuse deterrent opioid analgesic" means a brand name or generic opioid analgesic drug product that is:

(1) formulated with abuse deterrent properties; and

(2) supplied with abuse deterrent labeling that:

(A) is approved for the drug product by the federal Food and Drug Administration; and

(B) indicates that the drug product's abuse deterrent properties are expected to deter or reduce abuse of the drug product.

(c) As used in this section, "abuse deterrent properties" has the

meaning set forth in the federal Food and Drug Administration's document, Abuse Deterrent Opioids - Evaluation and Labeling, Guidance for Industry (April, 2015).

(d) As used in this section, "covered individual" means an individual who is entitled to coverage under a state employee health plan.

(e) As used in this section, "opioid analgesic drug product":

(1) means a drug product that:

(A) contains an opioid agonist active ingredient; and

(B) is indicated by the federal Food and Drug Administration for the treatment of pain; and

(2) includes:

(A) immediate release and extended release formulations of; and

(B) formulations that include another active ingredient in addition to the opioid agonist in;

a drug product described in subdivision (1).

(f) As used in this section, "state employee health plan" means one (1) of the following:

(1) A self-insurance program established under section 7(b) of this chapter to provide group health coverage.

(2) A contract with a prepaid health care delivery plan that is entered into or renewed under section 7(c) of this chapter.

(g) If there is available an abuse deterrent opioid analgesic that contains a particular opioid agonist active ingredient, a state employee health plan must provide coverage for at least one (1) abuse deterrent opioid analgesic containing that opioid agonist active ingredient.

(h) The coverage required by subsection (g) for a brand name abuse deterrent opioid analgesic must not be subject to dollar limits, copayments, deductibles, or coinsurance provisions that are less favorable to a covered individual than the lowest dollar limits, copayments, deductibles, or coinsurance provisions that apply to coverage for brand name prescription drugs generally under the state employee health plan.

(i) The coverage required by subsection (g) for a generic abuse deterrent opioid analgesic must not be subject to dollar limits, copayments, deductibles, or coinsurance provisions that are less favorable to a covered individual than the lowest dollar limits, copayments, deductibles, or coinsurance provisions that apply to coverage for generic prescription drugs generally under the state employee health plan.

(j) A state employee health plan:

(1) may not require a covered individual to first use an opioid analgesic drug product without abuse deterrent properties as a condition of coverage of an abuse deterrent opioid analgesic; and

(2) may apply utilization review requirements, including prior authorization, to coverage of an abuse deterrent opioid analgesic if the same utilization review requirements apply to all coverage of opioid analgesic drug products that have the same immediate release or extended release formulation as the abuse deterrent opioid analgesic.

(k) This section applies to a state employee health plan that is issued, entered into, delivered, amended, or renewed after June 30, 2016.

SECTION 2. IC 12-7-2-1.1 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 1.1. "Abuse deterrent opioid analgesic" means a brand name or generic opioid analgesic drug product that is supplied with abuse deterrent labeling that:**

(1) is approved for the drug product by the federal Food and Drug Administration; and

(2) indicates that the drug product's abuse deterrent properties are expected to deter or reduce abuse of the drug product.

SECTION 3. IC 12-7-2-1.2 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 1.2. "Abuse deterrent properties" has the meaning set forth in the federal Food and Drug Administration's document, Abuse Deterrent Opioids - Evaluation and Labeling, Guidance for Industry (April, 2015).**

SECTION 4. IC 12-7-2-135.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 135.7. "Opioid analgesic drug product":**

(1) means a drug product that:

(A) contains an opioid agonist; and

(B) is indicated by the federal Food and Drug Administration for the treatment of pain; and

(2) includes:

(A) immediate release and extended release formulations of; and

(B) formulations that include another active ingredient in

addition to the opioid agonist in;

a drug product described in subdivision (1).

SECTION 5. IC 12-15-35.5-9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 9. (a) The requirements of this section apply to coverage for prescription drugs under a program described in section 1 of this chapter, whether directly or through a formulary, a drug list, or another similar method.**

(b) If there is available an abuse deterrent opioid analgesic that contains a particular opioid agonist active ingredient, the office shall provide coverage for at least one (1) abuse deterrent opioid analgesic containing that opioid agonist active ingredient.

(c) The coverage required by subsection (b) for a brand name abuse deterrent opioid analgesic must not be subject to a copayment that is less favorable to a recipient than the lowest copayment that applies to coverage for brand name prescription drugs generally under the program.

(d) The coverage required by subsection (b) for a generic abuse deterrent opioid analgesic must not be subject to a copayment that is less favorable to a recipient than the lowest copayment that applies to coverage for generic prescription drugs generally under the program.

(e) The office:

(1) may not require a recipient to first use an opioid analgesic drug product without abuse deterrent properties as a condition of coverage of an abuse deterrent opioid analgesic; and

(2) may apply utilization review requirements, including prior authorization, to coverage of an abuse deterrent opioid analgesic if the same utilization review requirements apply to all coverage of opioid analgesic drug products that have the same immediate release or extended release formulation as the abuse deterrent opioid analgesic.

SECTION 6. IC 27-8-32.2 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]:

Chapter 32.2. Coverage for Abuse Deterrent Opioid Analgesics

Sec. 1. This chapter applies to a policy of accident and sickness insurance that provides coverage for prescription drugs, whether directly or through a formulary, a drug list, or another similar method.

Sec. 2. As used in this chapter, "abuse deterrent opioid

analgesic" means a brand name or generic opioid analgesic drug product that is:

(1) formulated with abuse deterrent properties; and

(2) supplied with abuse deterrent labeling that:

(A) is approved for the drug product by the federal Food and Drug Administration; and

(B) indicates that the drug product's abuse deterrent properties are expected to deter or reduce abuse of the drug product.

Sec. 3. As used in this chapter, "abuse deterrent properties" has the meaning set forth in the federal Food and Drug Administration's document, Abuse Deterrent Opioids - Evaluation and Labeling, Guidance for Industry (April, 2015).

Sec. 4. As used in this chapter, "insured" means an individual who is entitled to coverage under a policy of accident and sickness insurance.

Sec. 5. As used in this chapter, "opioid analgesic drug product":

(1) means a drug product that:

(A) contains an opioid agonist; and

(B) is indicated by the federal Food and Drug Administration for the treatment of pain; and

(2) includes:

(A) immediate release and extended release formulations of; and

(B) formulations that include another active ingredient in addition to the opioid agonist in;

a drug product described in subdivision (1).

Sec. 6. As used in this chapter, "policy of accident and sickness insurance" has the meaning set forth in IC 27-8-5-1.

Sec. 7. If there is available an abuse deterrent opioid analgesic that contains a particular opioid agonist active ingredient, a policy of accident and sickness insurance must provide coverage for at least one (1) abuse deterrent opioid analgesic containing that opioid agonist active ingredient.

Sec. 8. The coverage required by section 7 of this chapter for a brand name abuse deterrent opioid analgesic must not be subject to dollar limits, copayments, deductibles, or coinsurance provisions that are less favorable to an insured than the lowest dollar limits, copayments, deductibles, or coinsurance provisions that apply to coverage for brand name prescription drugs generally under the policy of accident and sickness insurance.

Sec. 9. The coverage required by section 7 of this chapter for a

generic abuse deterrent opioid analgesic must not be subject to dollar limits, copayments, deductibles, or coinsurance provisions that are less favorable to an insured than the lowest dollar limits, copayments, deductibles, or coinsurance provisions that apply to coverage for generic prescription drugs generally under the policy of accident and sickness insurance.

Sec. 10. A policy of accident and sickness insurance:

(1) may not require an insured to first use an opioid analgesic drug product without abuse deterrent properties as a condition of coverage of an abuse deterrent opioid analgesic; and

(2) may apply utilization review requirements, including prior authorization, to coverage of an abuse deterrent opioid analgesic if the same utilization review requirements apply to all coverage of opioid analgesic drug products that have the same immediate release or extended release formulation as the abuse deterrent opioid analgesic.

Sec. 11. This chapter applies to a policy of accident and sickness insurance that is issued, delivered, amended, or renewed after June 30, 2016.

SECTION 7. IC 27-13-7-20.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 20.3. (a) This section applies to an individual contract or a group contract that provides coverage for prescription drugs, whether directly or through a formulary, a drug list, or another similar method.**

(b) As used in this section, "abuse deterrent opioid analgesic" means a brand name or generic opioid analgesic drug product that is:

(1) formulated with abuse deterrent properties; and

(2) supplied with abuse deterrent labeling that:

(A) is approved for the drug product by the federal Food and Drug Administration; and

(B) indicates that the drug product's abuse deterrent properties are expected to deter or reduce abuse of the drug product.

(c) As used in this section, "abuse deterrent properties" has the meaning set forth in the federal Food and Drug Administration's document, Abuse Deterrent Opioids - Evaluation and Labeling, Guidance for Industry (April, 2015).

(d) As used in this section, "opioid analgesic drug product":

(1) means a drug product that:

(A) contains an opioid agonist; and

(B) is indicated by the federal Food and Drug Administration for the treatment of pain; and

(2) includes:

(A) immediate release and extended release formulations of; and

(B) formulations that include another active ingredient in addition to the opioid agonist in;

a drug product described in subdivision (1).

(e) If there is available an abuse deterrent opioid analgesic that contains a particular opioid agonist active ingredient, an individual contract or a group contract must provide coverage for at least one (1) abuse deterrent opioid analgesic containing that opioid agonist active ingredient.

(f) The coverage required by subsection (e) for a brand name abuse deterrent opioid analgesic must not be subject to dollar limits, copayments, deductibles, or coinsurance provisions that are less favorable to an enrollee than the lowest dollar limits, copayments, deductibles, or coinsurance provisions that apply to coverage for brand name prescription drugs generally under the individual contract or the group contract.

(g) The coverage required by subsection (e) for a generic abuse deterrent opioid analgesic must not be subject to dollar limits, copayments, deductibles, or coinsurance provisions that are less favorable to an enrollee than the lowest dollar limits, copayments, deductibles, or coinsurance provisions that apply to coverage for generic prescription drugs generally under the individual contract or the group contract.

(h) An individual contract or a group contract:

(1) may not require an enrollee to first use an opioid analgesic drug product without abuse deterrent properties as a condition of coverage of an abuse deterrent opioid analgesic; and

(2) may apply utilization review requirements, including prior authorization, to coverage of an abuse deterrent opioid analgesic if the same utilization review requirements apply to all coverage of opioid analgesic drug products that have the same immediate release or extended release formulation as the abuse deterrent opioid analgesic.

(i) This section applies to an individual contract or a group contract that is entered into, delivered, amended, or renewed after June 30, 2016.